

AMENDED IN SENATE JUNE 8, 2005

AMENDED IN SENATE MAY 31, 2005

AMENDED IN SENATE MAY 23, 2005

AMENDED IN SENATE APRIL 26, 2005

## **Senate Constitutional Amendment**

**No. 13**

**Introduced by Senators Ortiz and Runner**

**(Coauthors: Senators Cox and Dutton)**

(Coauthors: Assembly Members Benoit, Garcia, Jones, Laird, Leno,  
and Yee)

March 17, 2005

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Senate Constitutional Amendment No. 13—A resolution to propose to the people of the State of California an amendment to the Constitution of the State, by amending Section 6 of, and by adding Sections 8 and 9 to, Article XXXV thereof, relating to biomedical research.

### LEGISLATIVE COUNSEL'S DIGEST

SCA 13, as amended, Ortiz. Biomedical research.

The California Stem Cell Research and Cures Act, an initiative measure, establishes the California Institute for Regenerative Medicine, the purpose of which is, among other things, to make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and medical procedures that will result in the cure for, or substantial mitigation of, diseases and injuries. Existing law authorizes the issuance of bonds, not to exceed \$3,000,000,000, for the purpose of funding this research.

Existing law establishes the Independent Citizen's Oversight Committee (ICOC), composed of appointed members, that is required to perform various functions and duties with regard to the operation of the institute. Existing law also establishes various working groups whose purposes are to make recommendations to the ICOC regarding the making of these grants and loans.

This measure would require the chair and vice chair and any appointed member of the Independent Citizen's Oversight Committee (ICOC), *and the president and each employee of the institute, and any member of any working or advisory group appointed to assist the institute or its governing body* to disclose his or her income investments, and interests in real property in the manner set forth in the Political Reform Act, or its successor, *and except for employees of the institute and any member of any working or advisory group appointed to assist the institute or its governing body, to divest themselves of, or place into a blind trust, any financial or real property interest held by that person in any organization that applies for funding from, or contracts with, the institute or in any organization with a substantial interest in stem cell therapy* *would require each member of a working or advisory group, appointed to assist the institute or its governing body, to disclose to the ICOC his or her income and investments in any entity that has sought funding from the institute or that is engaged in biomedical research.* It would also require the State Auditor to review the financial disclosures made by each member of a working or advisory group, in addition to the voting record of each member regarding recommendations for applications for research and facility grants and loan awards and regulatory standards, and submit an annual report to the Legislature containing findings on whether any of the votes made by these members may constitute, or have constituted, a conflict of interest, as defined.

This measure would require that records and meetings *of the ICOC, the institute, or the institute's governing body, and any working or advisory group appointed to assist the institute or its governing body* be subject to state open meeting and public record laws that are applicable to state agencies, with certain exceptions.

This measure would require ~~every contract, award, grant, loan, or other arrangement entered into by the institute or the ICOC to ensure that these financial arrangements do not result in a gift of public funds, that loan, lease, or rental arrangement terms are consistent with or below market rates for rent or interest, and that any clinical~~

~~treatments, products, or services resulting from the biomedical research are made available, at the costs of producing them, to California residents who are eligible to receive assistance through state and county health care and preventive health programs the ICOC, when negotiating or overseeing intellectual property agreements associated with technologies or inventions derived from grants awarded pursuant to the act, to seek to ensure that treatments, therapies, products, and services resulting from or utilizing these technologies and inventions are accessible and affordable to low-income residents, including those residents eligible for state and county-funded health care programs.~~

~~The measure would require these financial arrangements to provide that the state recoup the full amount of its legal and administrative costs incurred with respect to patenting and licensing activities related to biomedical research, would require that the state be provided with its share of royalties or licensing revenues, derived from the development of clinical treatments, products, or services resulting from the research, that is sufficient to repay its expenses incurred in developing these treatments, products, or services, and would also require that these royalties or licensing revenues be transmitted to the state in an amount sufficient to repay the costs of issuing bonds incurred by the state in funding the biomedical research.~~

Vote:  $\frac{2}{3}$ . Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

1     *Resolved by the Senate, the Assembly concurring,* That the  
2     Legislature of the State of California at its 2005-06 Regular  
3     Session commencing on the sixth day of December 2004,  
4     two-thirds of the membership of each house concurring, hereby  
5     proposes to the people of the State of California, that the  
6     Constitution of the State be amended as follows:

7     First—That Section 6 of Article XXXV thereof is amended to  
8     read:

9     SEC. 6. ~~Except as otherwise provided in this article,~~  
10    ~~notwithstanding~~ *Notwithstanding* any other provision of this  
11    Constitution or any law, the institute, which is established in state  
12    government, may utilize state issued tax-exempt and taxable  
13    bonds to fund its operations, medical and scientific research,  
14    including therapy development through clinical trials, and  
15    facilities.

1 Second—That Section 8 is added to Article XXXV thereof, to  
2 read:

3 SEC. 8. (a) The chair and vice chair and any appointed  
4 member of the Independent Citizen's Oversight Committee  
5 (ICOC), and the president and each employee of the institute  
6 shall disclose his or her income, investments, and interests in real  
7 property in the manner set forth in Chapter 7 (commencing with  
8 Section 87100) of Title 9 of the Government Code, or its  
9 successor. ~~The chair and vice chair and any appointed member of~~  
10 ~~the ICOC, and the president of the institute shall divest~~  
11 ~~themselves of or place into a blind trust, any financial or real~~  
12 ~~property interest held by that person in any organization that~~  
13 ~~applies for funding from, or contracts with, the institute or in any~~  
14 ~~organization with a substantial interest in stem cell therapy. An~~  
15 ~~organization with a substantial interest in stem cell therapy is one~~  
16 ~~for which, based upon publicly available information, more than~~  
17 ~~five percent of the organization's current annual research budget~~  
18 ~~is allocated to stem cell therapy.~~

19 (b) (1) Upon his or her appointment and each year at a time  
20 specified by the ICOC, each member of a working or advisory  
21 group appointed to assist the institute or its governing body shall  
22 disclose to the ICOC his or her income, investments, and interest  
23 ~~in real property in the manner set forth in Chapter 7~~  
24 ~~(commencing with Section 87100) of Title 9 of the Government~~  
25 ~~Code, or its successor and investments in any entity that has~~  
26 ~~sought funding from the institute or that is engaged in biomedical~~  
27 ~~research.~~ The ICOC shall provide the disclosures to the State  
28 Auditor. The State Auditor, or his or her successor, shall review  
29 the disclosures, in addition to the voting record of each working  
30 or advisory group member regarding recommendations for  
31 applications for research and facility grants and loan awards and  
32 regulatory standards, and submit an annual report to the  
33 Legislature containing findings on whether any of the votes made  
34 by these members may constitute, or has constituted, a conflict of  
35 interest that requires or required the member to recuse himself or  
36 herself from consideration of an application or standard if the  
37 member is otherwise required under existing law to recuse  
38 himself or herself.

39 (2) For purposes of this subdivision, "conflict of interest"  
40 means the working or advisory group member, or a close relative

1 or professional associate of the member, has a financial or other  
2 interest in an application or standard that is known to the  
3 member, including a direct benefit of any amount deriving from  
4 an application or standard, or a financial benefit of any type from  
5 an applicant institution of over five thousand dollars (\$5,000) per  
6 year, including honoraria, fees, stock, or other benefits. For  
7 purposes of this paragraph, “close relative” and “professional  
8 associate” shall have the same meaning as those terms are  
9 defined under the National Institutes of Health Conflict of  
10 Interest, Confidentiality and Non Disclosure Rules.

11 (c) (1) Except as provided in paragraphs (2), (3), and (4),  
12 meetings and records of the institute, the ICOC, or any body  
13 established to govern the institute, and any working or advisory  
14 group *appointed to assist the institute or its governing body*, are  
15 subject to California open meeting and public record laws that  
16 are applicable to state agencies.

17 ~~(2) Notwithstanding paragraph (1), any working or advisory~~  
18 ~~group appointed to assist the institute or its governing body that~~  
19 ~~is charged with reviewing and recommending medical research~~  
20 ~~projects for funding may hold closed sessions when necessary to~~  
21 ~~conduct or carry out scientific peer review of any research project~~  
22 ~~submitted for funding, or for the purpose of considering or~~  
23 ~~discussing matters involving intellectual property or proprietary~~  
24 ~~information and matters involving prepublication confidential~~  
25 ~~scientific information associated with individual research~~  
26 ~~proposals submitted for funding. However, any working or~~  
27 ~~advisory group that is charged with reviewing and~~  
28 ~~recommending medical research projects for funding shall~~  
29 ~~produce a written summary that shall be a public record of the~~  
30 ~~reasons for recommending or not recommending any project for~~  
31 ~~funding as well as how each project recommended for funding~~  
32 ~~will benefit residents of California. The working or advisory~~  
33 ~~group shall hold an open session to allow public comment on its~~  
34 ~~decision prior to submitting any recommendation to the ICOC.~~

35 (2) (A) *Notwithstanding paragraph (1), any working or*  
36 *advisory group appointed to assist the institute or its governing*  
37 *body, that is charged with reviewing and recommending*  
38 *applications for funding, may hold closed sessions when*  
39 *necessary to conduct or carry out scientific evaluation of any*  
40 *application for research, training, or facility grants, loans, or*

1 *contracts submitted for funding. However, any working or*  
2 *advisory group that is charged with reviewing and*  
3 *recommending applications for research, training, or facility*  
4 *grants, loans, or contracts shall produce a written summary that*  
5 *shall be a public record of the reasons for recommending or not*  
6 *recommending any application for funding.*

7 *(B) The written summaries specified in subparagraph (A) shall*  
8 *be posted on the institute's Web site at least 10 days prior to the*  
9 *ICOC's consideration of any recommendations for funding and*  
10 *shall include, in the case of any application that is recommended*  
11 *for funding, the title and subject of the application, a description*  
12 *of how the project proposed in the application could benefit the*  
13 *State, a brief summary of the scientific review of the project, the*  
14 *consolidated scientific score for the project, and the final*  
15 *recommendation of the full working or advisory group on the*  
16 *application. In the case of any application that is not*  
17 *recommended for funding, the posted summaries shall include a*  
18 *short description of the project proposed in the application, the*  
19 *disease category addressed by the proposed project, the*  
20 *geographic region represented by that project, and the general*  
21 *reasons for the decision not to recommend the application for*  
22 *funding.*

23 *(3) Notwithstanding paragraph (1), the institute, ICOC, or any*  
24 *body established to govern the institute, and any working group*  
25 *or advisory group, may conduct closed sessions as permitted by*  
26 *the Bagley-Keene Open Meeting Act (Article 9 (commencing*  
27 *with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title*  
28 *2 of the Government Code), or its successor, and as permitted by*  
29 *Section 125290.30 of the Health and Safety Code, or its*  
30 *successor.*

31 ~~*(4) Notwithstanding paragraph (1), records containing*~~  
32 ~~*intellectual property or proprietary information and matters*~~  
33 ~~*involving prepublication of confidential scientific information*~~  
34 ~~*shall not be subject to public record laws.*~~

35 *(4) Notwithstanding paragraph (1), the institute, the ICOC, or*  
36 *any body established to govern the institute, and any working*  
37 *group or advisory group, may withhold records as permitted by*  
38 *the California Public Records Act (Chapter 3.5 (commencing*  
39 *with Section 6250) of Division 7 of Title 1 of the Government*  
40 *Code), or its successor and, where withholding is not otherwise*

1 *permitted by the California Public Records Act or its successor,*  
 2 *may withhold records relating to patients or medical subjects,*  
 3 *the disclosure of which would constitute an unwarranted*  
 4 *invasion of personal privacy, records containing or reflecting*  
 5 *confidential intellectual property or work product, and records of*  
 6 *prepublication, confidential scientific working papers or*  
 7 *research data.*

8 Third—That Section 9 is added to Article XXXV thereof, to  
 9 read:

10 SEC. 9. (a) ~~Every contract, award, grant, loan, or other~~  
 11 ~~arrangement entered into by the institute or the Independent~~  
 12 ~~Citizen's Oversight Committee shall ensure all of the following:~~  
 13 *When negotiating or overseeing intellectual property agreements*  
 14 *associated with technologies or inventions derived from grants*  
 15 *awarded pursuant to the California Stem Cell Research and*  
 16 *Cures Act, the ICOC shall seek to ensure that treatments,*  
 17 *therapies, products, and services resulting from or utilizing these*  
 18 *technologies and inventions are accessible and affordable to*  
 19 *low-income residents, including those residents eligible for state*  
 20 *and county-funded health care programs.*

21 (1) ~~Notwithstanding Section 6, the contract, award, grant,~~  
 22 ~~loan, or other arrangement does not result in a gift of public~~  
 23 ~~funds within the meaning of Section 6 of Article XVI.~~

24 (2) ~~All clinical treatments, products, or services resulting from~~  
 25 ~~the biomedical research are made available at the costs of~~  
 26 ~~producing them to California residents who are eligible to receive~~  
 27 ~~assistance through state and county health care and preventive~~  
 28 ~~health programs including, but not limited to, the Medi-Cal and~~  
 29 ~~Healthy Families programs.~~

30 (3) ~~The terms of any loan, lease, or rental arrangement are~~  
 31 ~~consistent with, or below, market rates for rent or interest.~~

32 (4) ~~The State recoups the full amount of its legal and~~  
 33 ~~administrative costs incurred with respect to patenting and~~  
 34 ~~licensing activities related to the biomedical research.~~

35 (5) ~~The State is provided a share of the royalties or revenues,~~  
 36 ~~derived from the development of clinical treatments, products, or~~  
 37 ~~services resulting from the research, that is sufficient to repay its~~  
 38 ~~expenses incurred in developing the clinical treatments, products,~~  
 39 ~~or services.~~

1     ~~(6) In addition to royalties or licensing revenues described in~~  
2     ~~paragraph (5), royalties or licensing revenues are transmitted to~~  
3     ~~the State in an amount sufficient to repay any costs of issuing~~  
4     ~~bonds incurred by the State in funding the biomedical research.~~

5     (b) Nothing in this section shall be construed to preclude the  
6     State from receiving any other benefits to which it would  
7     otherwise be entitled under Chapter 3 (commencing with Section  
8     125290.10) of Part 5 of Division 106 of the Health and Safety  
9     Code, or its successor.